MAR 1 5 2001

K010103

SURSHIELD™ WINGED INFUSION SET
Section II – Summary & Certification

SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION PERTAINING TO SUBSTANTIAL EQUIVALENCE

DEVICE NAME

Proprietary Name

SURSHIELD™ Winged Infusion Set

Classification Name

Intravascular Administration Set (80FPA)
21CFR, Section 880.5440
Classification: Class II

Common Name

I.V. Administration Set

INTENDED USE

The Surshield Winged Infusion Set is a device with flexible tubing intended for intravenous administration of fluids and/or withdrawal of blood specimens using a syringe, luer adapter, or other compatible/appropriate devices. The winged infusion set may be used for any patient population with consideration given to patient size. Additionally, after withdrawal of the needle from the patient's vein, the shield cover can be manually activated to cover the needle to minimize risk of accidental needlestick.

DESCRIPTION

The Surshield Winged Infusion Set is a sterile, single-use device consisting of a needle attached to a winged type hub, tubing, connector and connector cap, or injection port, and a hinged shield cover that attaches to the wing just below the needle-to-wing junction. The Surshield Winged Infusion Set is the same as the SURFLO® Winged Infusion Set (K771204 and K891063) except for the hinged shield cover safety feature.

The shield cover can be turned 180 degrees on the hinge. As the needle is removed from the patient's vessel, the user's finger actively pushes the shield cover until it latches onto needle using a single-handed technique. An audible click is noted upon activation. The shield cover is designed to allow the user's finger to remain behind the needle point so that the risk of needle stick injury is minimized. The shield cover is transparent for easy confirmation of the needle held in it.

Surshield Winged Infusion Set is available in 16 sizes with different combinations of four needle gauge sizes (19, 21, 23, 25g), two needle lengths (3/4"/ 19mm and 5/8"/16mm), two types of winged hubs (C=large for 19mm needles / D=small for 16mm needles), and two tube lengths (90mm and 300mm).

There are two types of connectors; a luer lock and an intermittent (injection plug). The luer lock device possesses both 90 and 300mm length tubing and the intermittent device possesses tubing 90mm in length.

SUBSTANTIAL EQUIVALENCE

The Surshield Winged Infusion Set is substantially equivalent to the following:

1. Becton-Dickinson VACUTAINER® Brand Safety-Lok™ Blood Collection Set (K980414)
2. Becton-Dickinson Saf-T E-Z Set™ (K970259)
3. Terumo Surflo® Winged Infusion Set – No safety feature - (K771204 and K891063)

PRINCIPLE OF OPERATION/TECHNOLOGY

This device is operated manually.

MATERIALS

The materials used in the Surshield Winged Infusion Set are substantially equivalent to the predicate devices. Any differences in materials do not raise any new issues of safety or effectiveness.

SURSHIELD™ WINGED INFUSION SET
Section II – Summary & Certification

SPECIFICATIONS

LUER LOCK TYPE

Cannula gauge	Color code	Product code	Winged type hub	Cannula length	Tube length
19G	Yellow	SV*S19BL	C type	3/4"(19mm)	300mm±10%
		SV*S19DL	D type	5/8"(16mm)	
		SV*S19BLS	C type	3/4"(19mm)	90mm±10%
21G	Green	SV*S21BL	C type	3/4"(19mm)	300mm±10%
		SV*S21DL	D type	5/8"(16mm)	
		SV*S21BLS	C type	3/4"(19mm)	90mm±10%
23G	Light blue	SV*S23BL	C type	3/4"(19mm)	300mm±10%
		SV*S23DL	D type	5/8"(16mm)	
		SV*S23BLS	C type	3/4"(19mm)	90mm±10%
25G	Orange	SV*S25BL	C type	3/4"(19mm)	300mm±10%
		SV*S25DL	D type	5/8"(16mm)	
		SV*S25BLS	C type	3/4"(19mm)	90mm±10%

INTERMITTENT TYPE

Code	**Color Code**	**Gauge / wing type**	**Needle Length**	**Tubing Length**
SV*S19BI	Yellow	19g / C type wing	¾" (19mm)	90mm ± 10%
SV*S19DI		19g / D type wing	5/8" (16mm)	
SV*S21BI	Green	21g / C type wing	¾" (19mm)	
SV*S21DI		21g / D type wing	5/8" (16mm)	
SV*S23BI	Light Blue	23g / C type wing	¾" (19mm)	
SV*S23DI		23g / D type wing	5/8" (16mm)	
SV*S25BI	Orange	25g / C type wing	¾" (19mm)	
SV*S25DI		25g / D type wing	5/8" (16mm)	

SURSHIELD™ WINGED INFUSION SET
Section II – Summary & Certification

PERFORMANCE

The following tests were performed on the Surshield Winged Infusion Set:

- Puncture Resistance of Shield Cover
- Force to lock the needle in the shield cover (Force to activate safety feature)
- Shield cover/Needle Locking Strength
- Break strength of the shield cover joint
- Flow Rate
- Simulated use study

Additionally, a risk analysis was conducted and any potential issues were addressed through design modification, and/or labeling. None of the data raises any new issues of safety and effectiveness.

The performance of the Surshield Winged Infusion device is substantially equivalent to the performance of BD's VACUTAINER® Brand Safety-Lok™ Blood Collection Set (K980414) and Saf-T E-Z Set™ (K970259), and the Terumo SURFLO® Winged Infusion Set (K771204 & K891063).

ADDITIONAL SAFETY INFORMATION

The sterilization conditions are validated according to EN550 to provide a Sterility Assurance Level (SAL) of 10^{-6}.

Ethylene Oxide residual levels resulting from EtO sterilization will not exceed the maximum residue levels proposed for Part 821 of Title 21 in the Federal Register Notice issued June 23, 1978, and indicated as follows:

Ethylene Oxide	25 ppm
Ethylene Chlorohydrin	25 ppm
Ethylene Glycol	250 ppm

The device's blood contacting materials were tested in accordance with the tests recommended in the FDA General Program Memorandum #G95-1 (5/1/95): Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part-1: Evaluation and Testing. Results of the testing demonstrate that the blood contacting materials are biocompatible.

SURSHIELD™ WINGED INFUSION SET
Section II – Summary & Certification

CONCLUSION

The Surshield Winged Infusion Set submitted in this Premarket notification is substantially equivalent to the VACUTAINER® Brand Safety-Lok™ Blood Collection Set (K980414), the Saf-T E-Z Set™ (970259) and the SURFLO® Winged Infusion Set (K771204 & K891063) with respect to intended use, design, technology/principles of operation, materials and performance. Differences between the devices do not raise any new issues of safety or effectiveness.

Date Prepared: 12/20/00

Prepared by: Barbara Smith
Regulatory Affairs Specialist
125 Blue Ball Rd
Elkton, MD 21921
Phone: 410-392-7241
Fax: 410-398-6079

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 5 2001

Ms. Barbara Smith
Regulatory Affairs Specialist
Terumo Medical Corporation
125 Blue Ball Road
Elkton, Maryland 21921

Re: K010103
Trade Name: Surshield™ Winged Infusion Set
Regulatory Class: II
Product Code: FPA
Dated: January 10, 2001
Received: January 12, 2001

Dear Ms. Smith:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does

not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K010103

Device Name: SURSHIELD™ WINGED INFUSION SET

Indications For Use:

The Surshield Winged Infusion Set is intended for intravenous administration of fluids and/or withdrawal of blood specimens using a syringe, luer adapter, or other compatible/appropriate devices. The winged infusion set may be used for any patient population with consideration given to patient size. Additionally, after withdrawal of the needle from the patient's vein, the shield cover can be manually activated to cover the needle to minimize risk of accidental needlestick.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K010103